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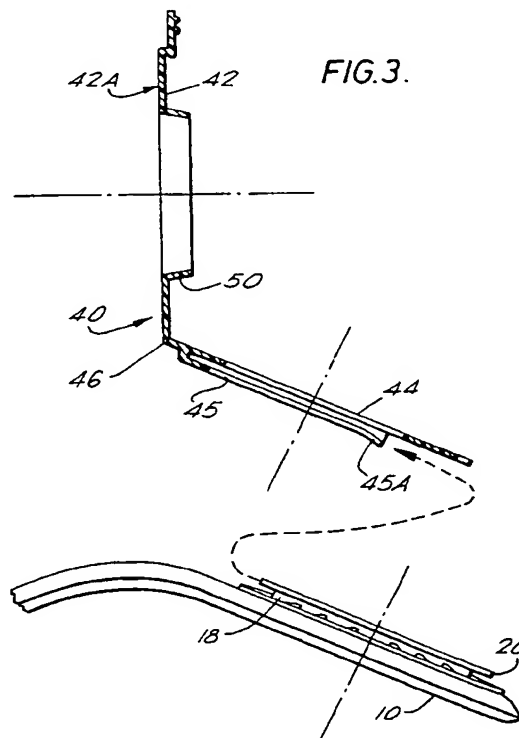
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(54) **Ostomy appliance.**

(57) An ostomy appliance principally is intended for use by obese persons who find it difficult or impossible to have a direct sight of the peristomal region to which an ostomy appliance is to be attached.

The ostomy appliance has a first coupling element (20) attached to an ostomy bag. The appliance also has a plate-like folding member having two leaves (44,42), of which the first leaf has a slot structure for receiving the first coupling element and the second leaf comprises a tubular conduit member (50) on one side thereof which is engagable in a sealing manner within the first coupling element, and on the other side (42A) thereof is provided with a pad of medical grade adhesive material.

The tubular conduit on the second leaf, when the two leaves are substantially parallel in their folded (closed) condition, is acting as a second coupling element. The second leaf is attached in any suitable manner to a pad of medical grade adhesive material.



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This invention relates to an ostomy appliance principally intended for use by obese persons who find it difficult or impossible to have a direct sight of the peristomal region to which an ostomy appliance is to be attached.

According to the present invention, there is provided an ostomy appliance having a first coupling element attached to an ostomy bag characterised by a plate-like folding member having two leaves, of which the first leaf has a slot structure for receiving the first coupling element and the second leaf comprises a tubular conduit member on one side thereof which is engagable in a sealing manner within the first coupling element, and on the other side thereof is provided with a pad of medical grade adhesive material.

With this construction it will be realised that the tubular conduit on the second leaf, when the two leaves are substantially parallel in their folded (closed) condition, is acting as a second coupling element. The second leaf is attached in any suitable manner to a pad of medical grade adhesive material which itself normally will be attached to the peristomal area of the wearer.

The principal advantage of this arrangement is that once the adhesive pad is in place on the wearer, and the bag side coupling element is placed in the slot on the first leaf, the wearer can fold closed the second leaf onto the first leaf, and be assured that the first and second coupling elements are properly and sealingly mutually engaged. This closure, due to the hinging action of the plate-like folding member, can readily be done by the wearer without direct sight of the location of the appliance. To the best of the present inventors' knowledge and belief, no ostomy appliance has hitherto been available wherein joining of the bag coupling to the pad coupling can be readily and reliably achieved without sight of the peristomal area. To further assure the wearer that the appliance is properly attached and accurately closed, and that the bag will not become accidentally detached, a latching arrangement is provided. In a preferred embodiment of the present invention, the latching arrangement comprises a detent tab on the second coupling element which co-operates with a portion of the distal end of the first leaf, this portion acting as counterpart detent tab.

In a preferred embodiment of the invention, both the plate-like folding member and the first coupling element on the bag may be made of a synthetic plastics material.

The invention will be better understood from the following non-limiting description of an example thereof given with reference to the accompanying drawings, in which:-

Figure 1 is a front view of the plate-like folding member shown in its closed condition;

Figure 2 is a front view similar to Figure 1 but showing the member in its open or unfolded position;

Figure 3 is a vertical cross-section, taken on the centre line of the plate-like member, showing it part-open; this Figure also shows a bag with a first coupling element thereon about to be lodged in the slot structure provided on the first leaf of the plate-like member;

Figure 4 is a cross section taken in a vertical plane showing the parts in their closed condition, corresponding to Figure 1; and

Figure 5 is a view half in cross-section taken on the line A-A of Figure 4 and half in side elevation and also shows the parts in the closed condition.

Referring firstly to Figures 1-5, the illustrated appliance includes a bag 10 (Figs. 4 and 5) having a stomal orifice 12, to which is attached a first coupling element 14. The element 14 is made of a synthetic plastics material and comprises a substantially flat flange 16, a ring-like wall 18 and a generally annular flange 20. Extending radially inwardly, from the inner edge of flange 20, is a flexible deflectible sealing strip 22 which extends completely around the stomal orifice defined by the encircling wall 18. The bag 10, which is usually made of a pair of sheets of plastics film suitably sealed around their periphery, is fixed to the left hand side surface (as seen in Figs. 4 and 5) of the flange 16 in any suitable way, for example by heat welding, RF welding or adhesive.

The second (also called body side) coupling element is seen best from Figures 1-3 and takes the form of a plate-like folding member having two leaves, of which the first leaf is provided with a slot structure for receiving the first (bag side) coupling element. The plate-like folding member 40 has a first leaf 42 and a second leaf 44. The leaf 44 has projecting therefrom a structure 45 which is L-shaped as seen in section and which curves around in an approximately U-shape as seen in elevation (Fig. 2). The purpose of this L-shaped wall, which defines a slot structure, is to receive the flange 20 of the bag side coupling element. The two leaves 42 and 44 are hinged together by a plastics hinge 46, as seen in Figures 2, 3 and 4. As seen in Figure 3, the wall 45, which is L-shaped as seen in the cross sectional view of Figure 4, has the two ends of the "U" formation angled slightly outwardly (as seen at 45A in Fig. 3) in order to provide an entry lead-in, facilitating insertion of the bag side coupling element into the slot defined by the structure 45. The leaf 42 includes a flat annular portion having a surface 42A to which is fixed, in any suitable manner, a pad 48, seen in Figures 4 and 5 only, of medical grade adhesive material. Suitable adhesive materials for this purpose include, for example, those described by Chen in U.S. Patent 3,339,546; by Chen et al. in U.S. Patent No. 4,192,785; by Pawelchak et al. in U.S. Patent No. 4,393,080; and by Doyle et al. in U.S. Patent No. 4,551,490. A particularly suitable material is that sold under the Registered Trade Mark

STOMAHESIVE by Bristol-Myers Squibb of Ickenham, Middlesex. As is conventional in ostomy couplings, provision may be made on the free surface of the medical grade adhesive pad for markings directed to assisting the user to cut out a central portion of the pad, in registry with the stomal orifice.

The pad 48 has a stomal orifice. The leaf 42 also has a shallow tubular protrusion 50 therefrom, having a wall tapering inwardly at a small angle, for example 10°. The wall is also shown at 50 in Figures 4 and 5. The outside diameter of the wall 50 at its inner or minimum diameter portion and its taper are chosen so that the wall 50 makes a good sealing fit with the sealing strip 22 of the bag side coupling element. In this way, the mouth of the space defined by the annular wall 50 is brought closely adjacent to and in registry with the stomal orifice 12 in the bag 10. As will be understood, this is achieved by folding over the leaf 44 by a raising motion, this being done after the bag side coupling element 20 has been snugly inserted within the slot structure 45.

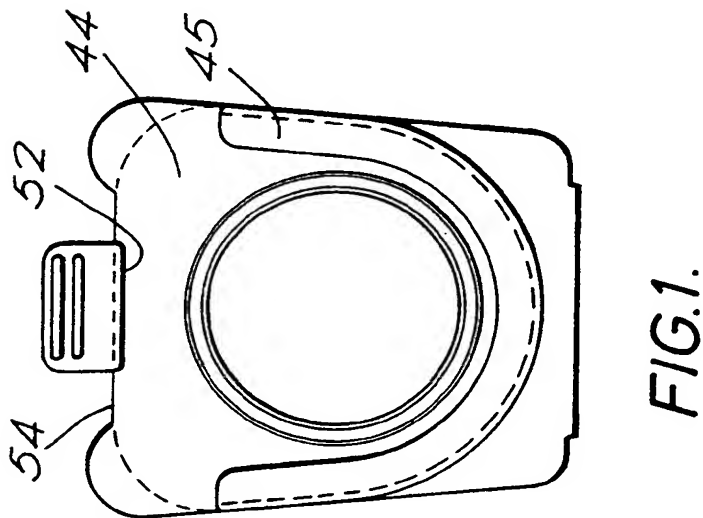
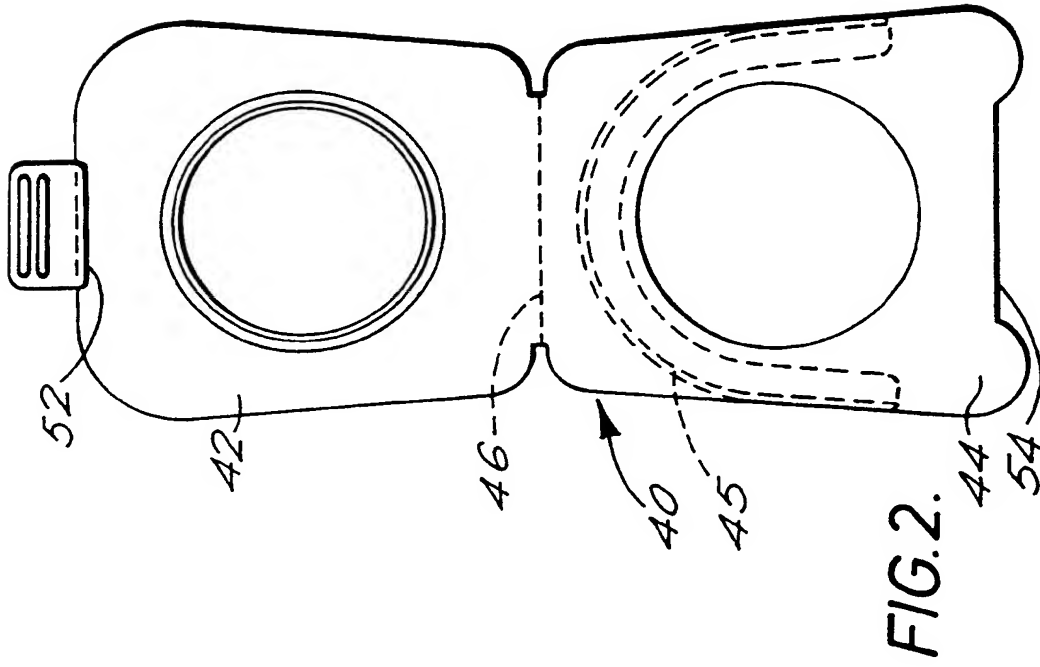
In order to latch the leaf member 44 closed, a latching detent 52 is provided on the leaf 42 of the body side coupling element. This detent 52 engages with a portion 54 (Fig. 2) of the edge of the leaf 44. This detent and surface are seen in the engaged position at the top of Figure 4.

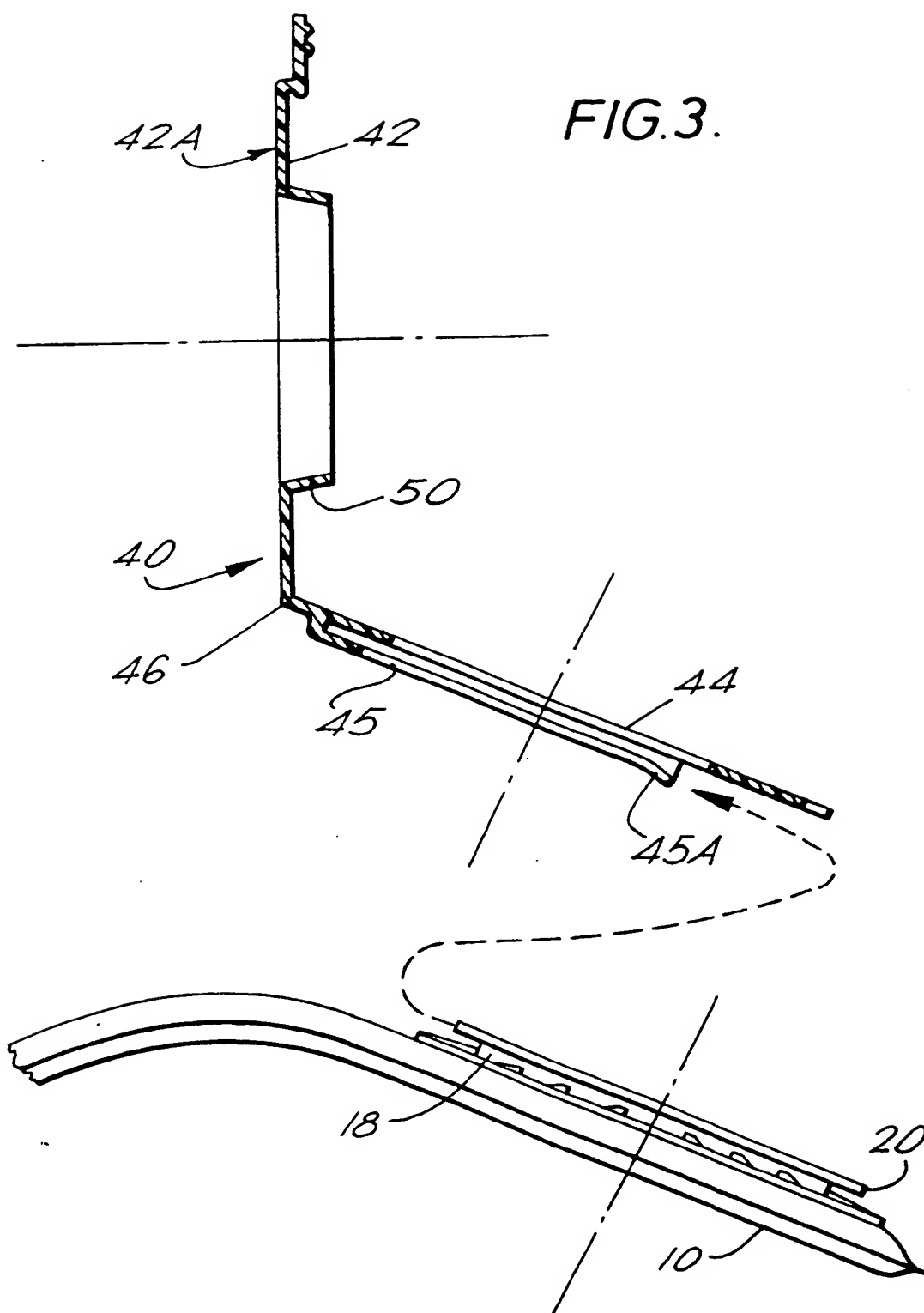
It will be seen that because of the provision of a body side coupling element in the form of a hinged foldable member, the path of movement of the bag side coupling element into engagement with the body side coupling element is an arcuate movement predetermined by the folding action, and the wearer of the appliance can therefore be secure in the knowledge that the bag side coupling element has been brought into proper aligned engagement with the body side coupling element and that the two parts are held together reliably by the detent arrangement 52. Consequently, it is no disadvantage for an obese wearer of this appliance to be unable to see the peristomal area where it is applied, since by manipulation of the folding action he or she can be assured of a proper joining of the bag and body side coupling elements.

A proposal has been made, in U.S. Patent 4 359 051, inventor Oczkowski, that a hanger means be added to an ostomy appliance to facilitate proper alignment and mating of the coupling elements and for preventing accidental dropping of the collection bag. The present invention provides a notable advance over Oczkowski's suggestion, and a simplification in design, in that the means of achieving proper alignment and coupling is an integral part of and is embodied in the structure of the body side coupling element. Moreover, Oczkowski's design is believed not to have been commercially successful.

Claims

1. An ostomy appliance having a first coupling element attached to an ostomy bag, the appliance being characterised by a plate-like folding member having two leaves, of which the first leaf has a slot structure for receiving the first coupling element and the second leaf comprises a tubular conduit member on one side thereof which is engagable in a sealing manner within the first coupling element, and on the other side thereof is provided with a pad of medical grade adhesive material.
2. An appliance according to claim 1 which includes a latching arrangement for holding the leaves closed.
3. An appliance according to claim 2 in which that latching arrangement comprises a detent tab on the second coupling element which co-operates with a portion of the distal end of the first leaf, this portion acting as counterpart detent tab.
4. An appliance according to any preceding claim in which both the plate-like folding member and the first coupling element on the bag are made of a synthetic plastics material.
5. An appliance according to any one of claims 1-4 in which the slot structure takes the form of an approximately U-shaped wall which is L-shaped as seen in cross-section.
6. A coupling element for use in an ostomy appliance which comprises a plate-like folding member having two leaves, the first leaf having a slot structure thereon for receiving a bag-side coupling element and the second leaf comprises a tubular conduit member constructed for engaging the bag-side coupling element in a sealing manner.
7. A coupling element according to claim 6 in which the slot structure takes the form of an approximately U-shaped wall which is L-shaped as seen in cross-section.
8. An ostomy appliance substantially as herein described with reference to and as illustrated in the accompanying drawings.
9. A coupling element for an ostomy appliance substantially as herein described with reference to and as illustrated in the accompanying drawings.
10. Any novel combination or sub-combination of features disclosed and/or illustrated herein.





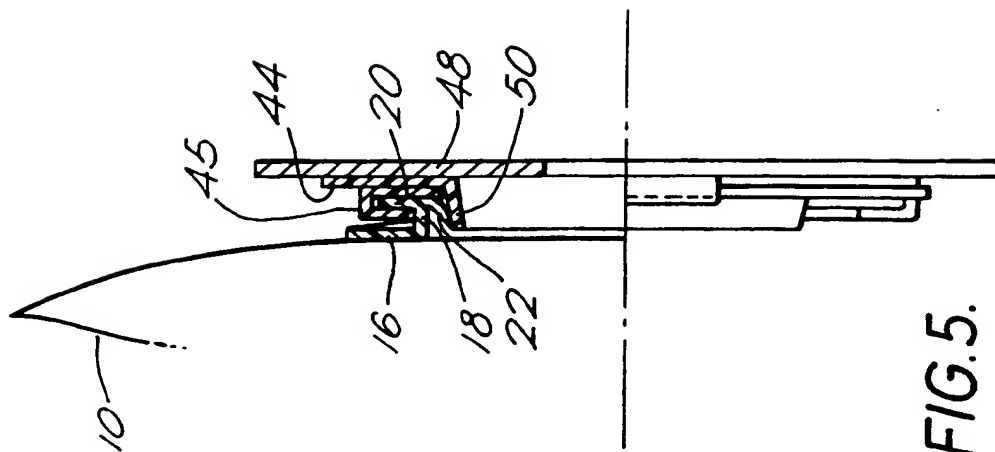


FIG. 5.

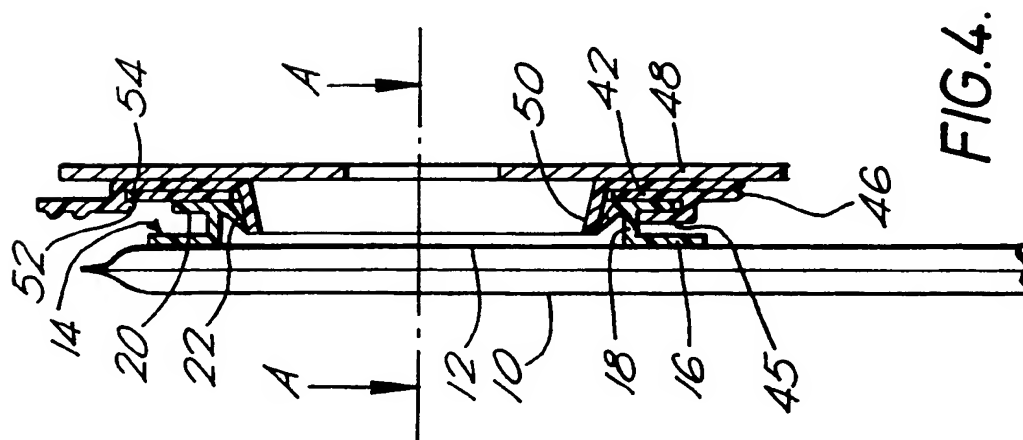


FIG. 4.



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 93 30 9238 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X,D Y	US-A-4 359 051 (OCZKOWSKI) * column 3, line 13 - column 4, line 59; figures 1-6 *	1,5-7 2-4	A61F5/448
Y	EP-A-0 277 821 (GRAIG MEDICAL) * abstract; figures 1,5,6 *	2-4	
A	US-A-4 294 252 (EINSET)		
A	US-A-5 026 360 (JOHNSEN ET AL.)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.5)
			A61F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims</p> <p>Claims searched completely : Claims searched incompletely : Claims not searched : Reason for the limitation of the search:</p> <p>see sheet C</p>			
Place of search		Date of completion of the search	Examiner
THE HAGUE		18 February 1994	Sanchez y Sanchez, J
CATEGORY OF CITED DOCUMENTS			
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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INCOMPLETE SEARCH

Claims searched completely : 1-7
Claims not searched : 8-10

Reason : Rule 29.6 EPC.